

## **Quality Assurance and Laboratory Accreditation Action Plan**

### **Issue Group: Laboratory Systems**

#### **Specific Activity Area being addressed by this Action Plan:**

In order to be internationally recognized as a leader in animal health, NVSL and CVB need to achieve ISO/IEC 17025 accreditation for selected areas/methods. NVSL and CVB need to assume a leadership role in supporting appropriate quality assurance improvement programs consistent with the ISO/IEC 17025 standard for laboratories. Appropriate quality assurance standards will be needed for assays deployed to the laboratories participating in the NAHLN.

#### **Safeguarding Review Recommendations Covered:**

- 18.** Upgrade the capabilities of the NVSL and the CVB for their critical role in the surveillance system.
- 95.** Ensure that critical agencies, personnel, and programs for the US diagnostic and applied research infrastructure are superlative, and that this diagnostic and applied research excellence is a critical agency priority for USDA.
- 119.** Develop and implement a quality assurance and control system for both federal and state laboratories that meets or exceeds international standards. Maintain and disseminate an active database of laboratories meeting these standards.

#### **Issue Group Findings:**

Currently neither NVSL nor CVB have any external accreditation status, even though this has been a long-standing goal for over 5 years. A revised QA plan has been formulated for NVSL and CVB's QA plan is in preparation. CVB has established a QA Unit within Inspection and Compliance. The unit will be staffed by one full-time Manager, up to three part-time auditor/inspectors, and one full-time document control clerk. Currently the Manager and two auditor/inspectors are in place. Five Laboratory Quality Manager positions were approved by the NVSL Position Management Team for recruitment; the FADDL and DVL Laboratory Quality Manager openings were announced in June 2004. NVSL and CVB remain vulnerable to criticism and scrutiny until accreditation is achieved, especially as the AAVLD labs are preparing to meet OIE standards by 2007.

#### **Proposed Actions:**

Make international accreditation for NVSL and CVB a more visible priority in VS as a whole as the AAVLD labs are attaining AAVLD accreditation which has incorporated OIE standards.

1. Follow through on existing QA Plan developed by NVSL and develop a formal QA plan for CVB
2. Develop and implement processes to assure that all products provided to NVSL and CVB's internal and external customers meet international standards.

## **Implementation Plan:**

1. Follow through on existing QA Plan developed by NVSL and develop a formal QA plan for CVB

- a. Prepare a Statement of Work and select a contract QA Coordinator for NVSL

**Responsible individual/group:** NVSL Director

**Timeline:** By end of CY 2004; contractor to start by January 2005

- b. Present plans, status of progress, and timelines for both NVSL and CVB QA programs to VSMT. Reaffirm that QA is a high priority within VS. Confirm VSMT support and acquire necessary resources.

**Responsible individual/group:** NVSL QA Coordinator and CVB QA Manager

**Timeline:** Target of March/April 2005 VSMT Meeting

- c. Hire NVSL and CVB required QA staff positions

**Responsible individual/group:** NVSL Laboratory Chiefs and CVB Management

**Timeline:** SRTL

2. Develop and implement processes to assure that all products provided to NVSL and CVB's internal and external customers meet international standards.

**Responsible individual/group:** All NVSL and CVB employees

**Timeline:** Ongoing

## Resources Needed

### Personnel

1 - Quality Assurance Coordinator (Contracted Employee) - \$100,000 to \$200,000 (NVSL)

5 – Laboratory Quality Assurance Staff GS 11/12 - \$381,320 (4 for NVSL; 1 for CVB)

1 – Document Clerk GS 6 - \$38,689 (CVB)

1 – QA Lab Staff GS-8 - \$47,614 (CVB)

(All estimates include salary plus benefits)

Training and Travel – 1st year - \$150,000 (NVSL and CVB)

Outside Auditor - \$15,000 per audit, up to 5 audits per year - \$75,000 (NVSL and CVB)

Total 1st year cost - \$892,623

#### Statutory/Regulatory Impacts

No impacts currently. However, full implementation of a quality assurance program may be required in the future.

#### Political Sensitivities:

Failure on the part of NVSL and CVB to implement an internationally recognized QA program will erode the stature of NVSL and CVB, as well as the NAHLN in the eyes of the international laboratory community. Some non-Federal laboratories are surpassing NVSL and CVB in the process of achieving international quality assurance standards. International accreditation may be required for future international movement of animals and animal products. NVSL and CVB must have international accreditation to remain credible.

#### Sequencing:

This action plan is an integral element in the success of the NAHLN and Test Validation Action Plans.

#### **Partnering/Cooperation/Communication:**

A QA program and accreditation allows NVSL and CVB to take a national and international leadership role through example, sharing their experiences with other diagnostic laboratories/biologics partners for whom QA is similar challenge.

#### **Expected Outcome and Performance Indicators:**

NVSL and CVB will achieve international accreditation in multiple tests and methods.

Products provided by NVSL and CVB will meet international standards.

Performance indicator: Number of accredited testing methods performed by NVSL and CVB

#### **Linkage to the VS Strategic Plan:**

The following Goals and Objectives are supported by the proposed actions.

Objective 2.6 – Improve laboratory diagnostic services, products and training to support animal disease surveillance.

Objective 3.2 – Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs.

Objective 3.3 – Ensure the availability of quality veterinary biological products for diagnosis, prevention and treatment of animal diseases.

Objective 4.3 – Provide disease-status certification for animal entering domestic or international trade.

Objective 4.4 – Improve diagnostic testing associated with the marketing of animals and animal products.